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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/774,985 | 02/09/2004 | Robert A. Rabiner | 20563/2422 | 9583 |
| 26161 | 7590 | 12/13/2005 | | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | EXAMINER HORWAT, JENNIFER A | |
| | | | ART UNIT 3737 | PAPER NUMBER |

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,985

Applicant(s)

RABINER ET AL.

Examiner

Jennifer Horwat

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/9/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 64-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 64-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/7/05 5/21/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-33 and 64-70 in the reply filed on 11/23/2005 is acknowledged.
2. Claims 34-63 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/23/2005.

Information Disclosure Statement

3. The information disclosure statements filed on 5/21/2004 and 1/7/2005 are in compliance with 37 CFR 1.97-1.98 and all references therein have been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 7, 9-11, 17, 19-22, 25, 26, 32, 64, 65, 68, 69 rejected under 35 U.S.C. 102(e) as being anticipated by Wuchinich (US 2001/0047166). Wuchinich discloses an ultrasonic medical device that creates torsional vibration (figure 4, element 40), which discloses all of the limitations of the above mentioned claims. The probe

comprises a proximal end coupled to a transducer (figure 1, element 1), a distal end, with a longitudinal axis between (figure 4), with an energy source engaged to the transducer producing ultrasonic energy (figure 1, elements 1 and 15). Torsional vibration, which by definition rotates and counterrotates the ultrasonic probe, propagates the length of the probe through the resonator resulting in a plurality of nodes (paragraph 12), which inherently result in a plurality of anti-nodes at half the distance between any two nodes. In the embodiment shown in figure 3, the longitudinal axis of the probe has a radially asymmetric cross section (figure 3, element 41). It is also possible for the axis to have an approximately rectangular cross section (paragraph 70) or have longitudinal grooves, which create a plurality of "flutes", or projections, extending along the length of the probe (paragraph 10). Additionally, the diameter of the probe can be tapered or varied from the proximal end to the distal end of the probe (figure 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Rabiner, et al (US 2002/0029054). Wuchinich, as discussed above, substantially discloses the invention as claimed, however does not explicitly

teach that the ultrasonic probe can be used to ablate biological material along the portion of the longitudinal axis comprising the radially asymmetric cross section.

Rabiner teaches that it is advantageous to use ultrasonic vibration along the longitudinal axis of an ultrasonic probe to destroy tissue along the length of the probe (paragraph 26) using cavitation in order to be less traumatic to surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in light of the teachings of the reference by Rabiner to provide decreased procedure time and less residual tissue damage (paragraph 26).

8. Claims 8, 12, 14-16, 24, 27, 29-31, 67, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Fenton (US 2003/0212331). Wuchinich, as discussed above, substantially discloses the invention as claimed, however fails to disclose the capability for flexibility of the probe and fails to explicitly disclose the operating frequency range of the device. Fenton also discloses an ultrasonic device capable of torsional vibration, which states that ultrasonic surgical instruments typically operate in the range of 20 to 100 kHz (paragraph 4). In addition, the vibration element of the probe disclosed in the reference by Fenton is "formed of a flexible, compliant material" which may "have a substantially curvilinear configuration" (paragraph 19). In another embodiment the probe has a substantially uniform cross section (figure 2A). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in light of the teachings of Fenton as flexibility and a curved shape in the probe allow the probe to reach a greater number of areas minimally invasively.

9. Claim 13, 28, 33, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, et al (US 2003/0045887). Wuchinich, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose operating at the resonant frequency of the transducer. Sakurai also discloses an ultrasonic probe capable of torsional vibration and teaches that "resonance-point tracking" is possible in order to set the resonance frequency to the frequency of the vibration oscillator (paragraph 77). Additionally, the elongated probe of the ultrasound device has an approximately circular cross section (figure 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich with the teachings of Sakurai to increase the efficiency of the device.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Jones (US 6433464). Wuchinich, as discussed above, substantially discloses the invention as claimed, however fails to teach that the device may be disposable. Jones discloses a device for dissolving and removing unwanted biologic materials using acoustic waves and teaches one advantage of the device is that it is optionally disposable (col 18, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich with the teachings of Jones in order to make the probe disposable in order to provide a device that is more convenient to use and does not require cleaning or sterilization.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jah
12/8/2005


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